MISSOURI BOARD OF PHARMACY

NEWSLETTER

AUGUST 2021

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NEW 2021 LEGISLATION

HIV PEP Dispensing:

Section 338.730 was recently enacted which allows pharmacists to dispense HIV postexposure prophylaxis pursuant to a protocol with a Missouri-licensed physician. Section 338.730.5 requires the Board of Pharmacy and the Board of Registration for the Healing Arts to jointly promulgate rules to implement the new provisions.

The Board of Pharmacy reviewed an initial rule draft at its recent August meeting. Once finalized, the Board of Healing Arts has to approve the rule. Both boards would then need to complete the rulemaking process which can take an additional 6-9 months (actual time may vary depending on rule changes/comments).

Pharmacists cannot dispense HIV postexposure prophylaxis by protocol until final rules have been promulgated. Monitor the Board's website for additional rule updates.

Prescription Drug Monitoring Program (PDMP):

Senate Bill 63 enacted a statewide Prescription Drug Monitoring Program (§ 195.450). The PDMP will be regulated by the Missouri Office of Administration and a Joint Oversight Task Force that includes members from the Board of Pharmacy, the Board of Nursing, the Board of Registration for the Healing Arts, and the Missouri Dental Board.

Although the new provisions are effective on August 28, 2021, the Joint Task Force still needs to establish the PDMP system and/or select a contract vendor. Licensees/registrants should monitor the Board's e-alert for additional PDMP developments. Section 195.450.15 provides the statewide PDMP will supercede any local laws/ordinances once the PDMP is operational. Once again, the newly enacted statewide PDMP is not operational at this time.

Interested licensees/registrants should continue to monitor the Board's website for additional updates.

RULE CHANGES/UPDATES

The following rules were recently enacted/amended by the Board:

- 20 CSR 2220-2.425 (Required Pharmacy Reporting): The rule establishes pharmacy reporting requirements to facilitate Board compliance with the U.S. Food and Drug Administration's State Compounding Memorandum of Understanding (MOU). Under the rule, Missouri-located pharmacies that have distributed or dispensed compounded human drug preparations/products pursuant to prescriptions/medication orders in the previous calendar year are required to annually report compounding data to the Board (see rule for specific reporting requirements).

  The FDA recently announced that it is extending the time period for states to comply with the compounding MOU. The Board will review the extension and provide additional compliance information/directions in the near future.

- 20 CSR 2220-2.685 (Class Q: Charitable Pharmacy): The new rule establishes licensing and operational requirements for Class Q Charitable pharmacies. A Class Q charitable pharmacy is defined as:

  > *A site in Missouri that is owned or operated by a charitable organization for purposes of providing pharmacy services to appropriately screened and qualified indigent patients.*

  Class Q pharmacies may only provide services to or for "qualified indigent patients", which are defined in the rule as:

  > *A patient of a charitable pharmacy that has been screened and approved by a charitable organization and deemed not to have sufficient funds to obtain needed medication based on the charitable organization's pre-established criteria.*

  20 CSR 2220-2.685 contains additional practices allowances to accommodate charitable pharmacy activities such as:

- Pharmacies with a Class Q permit may dispense non-controlled medication when a pharmacist is absent provided the prescription/medication order has been previously verified by a pharmacist, or the medication is provided to a healthcare provider for administration and bar code technology is used to verify the correct medication has been provided.**
- Class Q Charitable Pharmacies may accept and dispense donated medication received from a pharmacy, drug distributor, healthcare entity or a healthcare provider who is licensed to prescribe. Donated medication cannot be accepted from a patient or the public.** **Additional compliance requirements apply.

Interested parties should review 20 CSR 2220-2.685 for additional information/requirements. Once again, Class Q charitable pharmacies may only provide services to or for qualified indigent patients.

- 20 CSR 2220-6.050: Similar to the previously issued COVID-19 waiver, the rule has been officially amended to authorize qualified pharmacy technicians to administer vaccines by protocol under the direct supervision of a Missouri-licensed pharmacist who is authorized to immunize. The supervising pharmacist must be physically present on-site when the vaccine is administered.

  A qualified pharmacy technician is defined as a pharmacy technician who:

  1. Holds an active pharmacy technician certification issued by a certification entity accredited by the National Commission for Certifying Agencies;
  2. Has an initial and, if applicable, annual documented assessment of competency in vaccine administration; and
  3. Has assisted in the practice of pharmacy as a registered/licensed pharmacy technician in the state of Missouri or another U.S. state or territory for a minimum of one (1) year.

  Proof of technician compliance with the above requirements must be maintained by both the supervising pharmacist and the intern pharmacist/qualifying pharmacy technician for a minimum of two (2) years.

  Pharmacists supervising technician vaccine administration should ensure that technicians are not offering patient counseling, this includes advising patients of potential vaccine side effects or how to treat them (see Patient Counseling article below)

- 20 CSR 2220-7.025 (Intern Pharmacist Licensure): The rule has been amended to remove the previous 48-hour limit on the number of practice hours an intern pharmacist may earn per week. The rule amendment matches the COVID-19 waiver previously issued by Governor Parson.

NEW 2021 PRACTICE RESOURCES

The following practice resources have been updated and are now available on the Board's website:

- 2021 Pharmacy Practice Guide
- 2021 Pharmacy Self-Assessment Guide
- 2021 Pharmacy Practice Guide CE Quiz &
- 2021 Pharmacy Technician Guide

The 2021 Practice Guide can be downloaded for free on the Board's website. Courtesy copies of the Practice Guide will be mailed to all Missouri-located pharmacies.

Additional printed copies of the 2021 Practice Guide are available for $ 13.50. Requests/payment should be mailed to the Board office at:

Missouri Board of Pharmacy
3605 Missouri Boulevard
Jefferson City, Missouri
65109

Checks/money orders should be made payable to: The Missouri Board of Pharmacy.

PATIENT COUNSELING: A CAUTION

The confluence of market factors, effects from a global pandemic, and COVID-19 vaccine administrations have made busy pharmacies busier than ever, and with that has come an increase in inspection violations related to patient counseling. Inspectors have observed multiple instances of technicians providing patient counseling. In many instances, the pharmacist on duty was aware of the technician's actions but did not realize it crossed the line into patient counseling. Some recent examples instances include:

- Technicians answering questions about the medication's indication,
- Technicians recommending over-the-counter (OTC) products to treat a specific ailment,
- Technicians explaining medication storage and administration (even when this information is being read from the prescription label or auxiliary labels), and
- Technicians informing patients of side effects they may experience following administration of a COVID-19 vaccine or how to treat them.

Take time this month to discuss the delineation between pharmacist and technician duties with your staff, and to remind staff what constitutes patient counseling.

BE ON ALERT FOR FRADULENT PRESCRIPTIONS

An astute pharmacist recently discovered two fraudulent prescriptions had been faxed to his pharmacy. The prescriptions in question were written for an antibiotic and a controlled cough syrup. They were received as a single fax consisting of two pages for a single patient, and were in familiar prescription format with standard directions and quantities.

Fortunately, the pharmacist noticed the prescriber signatures on the two prescriptions appeared identical, which is often indicative of an electronic signature. Federal regulations prohibit the conversion of an electronic controlled substance prescription to facsimile for transmission (21 CFR 1311.170(f)). The pharmacist attempted to call the prescriber using a phone number already on file with the pharmacy and learned the prescription was fraudulent and that several other pharmacies in the state had received similar fraudulent prescriptions.

A review of the fraudulent prescriptions revealed multiple warning signs, including:

- The patient was unknown to the pharmacy, despite supposedly being located in the same small, rural town;
- The prescriber was an emergency department physician located nearly 200 miles from the patient's address and the receiving pharmacy;
- The area code on the fax header indicated the prescription was from northern Alabama, but the prescription header indicated the prescription was from a Missouri practice site;
- Multiple fonts and font sizes were used within each prescription;
- Inconsistent font, font size, spacing, capitalization, and phrasing were noted when comparing the two prescriptions;
- Improper/inaccurate use of punctuation; and
- The prescriber signature was on the "Dispense as written" line, even though generic products were specifically prescribed.

While none of these confirm a prescription as fraudulent, they should elicit additional scrutiny.

Take time this month to review fraudulent prescription warning signs with your staff, and remind them that when in doubt, call the prescriber using a known/verified number to confirm the prescription's legitimacy. Your vigilance is key to protecting Missouri citizens from illegal/illegitimate drug use.

Upcoming 2021 Board Meetings:

- October 19-20th
- November 17th
- December 5th

*The Board will not be meeting in September.

Due to COVID-19 precautions, public attendees can virtually attend the above Board meetings via WebEx. Meeting information will be available on the Board's website approximately 1-week before the meeting, including instructions/links for participating in the meeting.

UPCOMING BOARD DISCUSSION ITEMS

- Pharmacy Workforce Conditions
- Class K Internet Pharmacy Definition
- Pharmacist Dispensing of HIV Postexposure Prophylaxis
- Technology Assisted Final Product Verification
- Pharmacy Standards of Operation
- Electronic Patient Counseling Offers

Visit the Board's website for additional meeting/agenda information.

UPCOMING LUNCH WITH THE CHIEF INSPECTOR WEBINARS

- September 23 - Compliance Update/Q&A Session
- October 7 - MO HealthNet Update

GOLD CERTIFICATES:

Congratulations to our newest "gold certificate" pharmacists who will have maintained a Missouri pharmacist license for 50 years:

Robert L Alexander
Michael M Eckert
Tedd H Kimelman
Frank J Nuber
George L Oestreich***
Paul J Schnedier Jr
Thomas R Wooten

***Former Missouri Board of Pharmacy Member (5-years) and past Board President.

DISCIPLINARY ACTIONS

DRUG DISTRIBUTORS:

The Hilsinger Company Parent LLC d/b/a Hilco Vision, #2021021107, - Plainville, MA. Drug distributor license issued on two (2) years probation. Operated without a valid license. Section 338.055.2(6), RSMo.

PHARMACISTS:

Lammert, Jennifer L., #044186, St. Louis, MO. Public Censure. As pharmacist-in-charge reuse of medications from returned multi-dose medication packages Section 338.055.2(5), (6), (13), and (15), RSMo.

Glen F. Palmer, #2018008573, Clarksburg, WV. One (1) year suspension followed by five (5) years probation. Pharmacist's West Virginia pharmacist license was reprimanded and suspended for diverting hydrocodone/APAP 10/325 mg from the pharmacy. Pharmacist's Virginia license was also suspended as a result of the disciplinary action in West Virginia. Section 338.055.2 (5), (8), (13), (15), and (17), RSMo.

Wallace, Keith, #2001019315, St. Peters, MO. Public Censure. As pharmacist-in-charge reuse of medications from returned multi-dose medication packages Section 338.055.2(5), (6), (13), and (15), RSMo.

PHARMACIES:

Tara Pharmacy-Midwest, St. Louis, MO. Two (2) years probation. Reuse of medications from returned multi-dose medication packages. Section 338.055.2(5), (6), (13), and (15), RSMo.

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY® NATIONAL PHARMACY COMPLIANCE NEWS - JANUARY 2021

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NEW WEB PAGE ADDRESSES BOARDS' QUESTIONS ON FDA MOU FOR COMPOUNDED PRODUCTS

Food and Drug Administration (FDA) has created a new web page to help answer questions regarding the Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products from boards of pharmacy and other state agencies. The web page will continue to be updated by FDA as additional questions on the MOU are received. FDA worked with NABP to develop a standard MOU for use by the state boards of pharmacy to assist with their compliance of section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act. As part of the MOU, boards must identify pharmacies that are compounding human drug products and distributing inordinate amounts of such products interstate and report those pharmacies to FDA. Additional resources and information on the FDA MOU and the Compounding Pharmacy Information Sharing Project can be found through the Members section of the NABP website.

PHARMACIES CAN ADDRESS THESE TWO HAZARDS TO IMPROVE SAFETY PROGRAMS

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at www.ismp.org.

Every pharmacy should strive to continually improve their medication-use system and provide the safest, highest quality of care possible. To accomplish this, practice sites must assess their risks associated with the medication-use process by monitoring actual and potential medication errors and adverse drug events. Below are two issues that warrant attention and priority if you have not already taken action to mitigate the risk.

SELECTING THE WRONG MEDICATION AFTER ENTERING ONLY THE FIRST FEW LETTERS OF THE DRUG NAME

Entering just the first few letter characters of a drug name, or a combination of the first few letters and product strength, potentially allows the presentation of similar looking drug names on computer order entry screens. This increases the risk of selection errors. Examples of drug selection errors that resulted after entering the first few letters of the drug name include mix-ups between Ambien® (zolpidem) and ambrisentan; Briviact® (brivaracetam) and Brilinta® (ticagrelor); and tramadol and trazodone. Also, entering "met" has often led to confusion between methylphenidate, methadone, metolazone, methotrexate, metformin, and metronidazole; and entering "meth10" has led to confusion between methadone 10 mg and methylphenidate 10 mg.

Guard against these errors by entering a minimum of the first five letters of a drug name during product searches, which will reduce the number of similar names that appear together on the same screen. Work with your information technology staff and computer vendor to implement this recommendation. Until then, practitioner awareness of this problem may help change personal practice habits.

DAILY INSTEAD OF WEEKLY ORAL METHOTREXATE FOR NON-ONCOLOGIC CONDITIONS

Prescribing, dispensing, or administering oral methotrexate daily instead of weekly for non-oncologic conditions continues. A December 2019 QuarterWatch analysis of inadvertent daily methotrexate administration over 18 months between 2018 and 2019 demonstrated that about half of the reported errors were made by older patients who were confused about the frequency of administration, and the other half were made by health care providers who inadvertently prescribed, labeled, or dispensed methotrexate daily when weekly was intended.1 An analysis sponsored by United States FDA suggests that up to four per 1,000 patients may mistakenly take the drug daily instead of weekly.2

Other causes of methotrexate wrong frequency errors more recently reported to ISMP include:

- A mix-up between the look-alike, round, yellow tablets of methotrexate and folic acid, the latter of which is often prescribed with methotrexate to lessen its toxicity
- A fatal mix-up between metolazone 2.5 mg, the intended drug, and methotrexate 2.5 mg, caused in part by entering just "met" into the order entry system and selecting the wrong drug from the search menu
- A fatal mix-up between Paxil® (paroxetine) 10 mg, the intended drug, and Trexall® (methotrexate) 10 mg, caused by mishearing a prescription called in to a community pharmacy

To reduce the risk of error, consider the following strategies:

- implement computer systems that default to a weekly dosage regimen when entering electronic orders or prescriptions for oral methotrexate;
- require an appropriate oncologic indication for all daily methotrexate orders; and
- provide patient and family education about the importance of weekly administration. To assist with education, provide patients and families with a copy of ISMP's free consumer leaflet on oral methotrexate.

References

Moore TJ, Furberg CD, Mattison DR, Cohen MR. QuarterWatch 2019 quarter 2: Scope of injury from therapeutic drugs. Institute for Safe Medication Practices. 4 Dec 2019.

Herrinton LJ, Woodworth TS, Eworuke E, et al. Development of an algorithm to detect methotrexate wrong frequency error using computerized health care data. Pharmacoepidemiol Drug Saf. 2019 Oct;28(10):1361-1368.

SURVEY: MOST PHARMACISTS UNFAMILIAR WITH SAFE ONLINE PHARMACY RESOURCES

The results of a survey of United States pharmacists published in the journal Medicine Access @ Point of Care indicate that 58% of respondents lacked confidence in identifying and counseling patients on illegal pharmacy websites. Further, fewer than 60% of pharmacists were able to accurately identify whether a web page was legitimate, and 75% of pharmacists reported being unfamiliar with resources available to help consumers identify safe and legitimate online pharmacies.

Pharmacists can help protect consumers who shop for medications online by directing them to always buy from NABP-verified websites. A list of safe online pharmacies and related resources can be found in the Buy Safely section of NABP's consumer website, www.safe.pharmacy.

HHS EXPANDS ACCESS TOWARD LIFESAVING ADDICTION TREATMENT

The United States Department of Health and Human Services (HHS) has expanded practice guidelines allowing certain practitioners who are state licensed and registered by Drug Enforcement Administration (DEA) to have the ability to more easily prescribe buprenorphine to patients with opioid use disorder (OUD). The expansion scales back the DEA "X-waiver" to further expand patient access to the lifesaving medication. NABP and bipartisan lawmakers continue to push for Congress to pass the Mainstreaming Addiction Treatment Act (MAT Act), which would permanently remove the DEA X-waiver and lay the groundwork for states to utilize pharmacists to provide medication-assisted treatment (MAT).

As part of his 2020-2021 presidential initiative, former NABP President Timothy D. Fensky, RPh, DPh, FACA, along with NABP and its member boards, have urged Congress to pass the MAT Act to allow states to recognize pharmacists as MAT providers for patients diagnosed with OUD.

SCAM TARGETING PHARMACISTS – DEA WARNS

Drug Enforcement Administration (DEA) has issued a warning about a scam that is targeting pharmacists in different regions of the United States. In a recent case, a pharmacist received a phone call from an individual who claimed to be from the Federal Bureau of Investigation (FBI) and told the pharmacist that their license was currently under investigation. According to DEA, the scammer warned the pharmacist to not let anyone know about the call and to leave the pharmacy saying they had an urgent family matter, so they could go to the post office to receive faxed details of the FBI investigation. The scammer told the pharmacist that they were being watched and to remain on the phone until receiving the documents at the post office. The pharmacist was also directed to send $18,000 to the scammer.

The above-mentioned scam is just one version of a much broader scam targeting health care providers. Scammers are also claiming to be board of pharmacy investigators in order to obtain sensitive personal information and money over the phone.

DEA warns pharmacists and other health care providers to be alert, and that scams can appear in many different forms. Always report anything suspicious to DEA or the FBI.

NATIONWIDE RECALL ISSUED FOR ACETAMINOPHEN EXTRA STRENGTH TABLETS DUE TO MISLABELING

A-S Medication Solutions, LLC (ASM) is voluntarily recalling 198,350 bottles of acetaminophen extra strength 500 mg tablets, 100-count bottles to the consumer level. The product, which was included in a Health Essentials Kit distributed by Humana to its members, contained an incomplete drug label rather than the required over-the-counter drug facts label.

ASM has been notifying its distributors and customers by mail and arranging the return of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to Food and Drug Administration's MedWatch Adverse Event Reporting program.